

RESPONSE

Claims 15-19, 22-41, and 61-65 are pending in the present application. New claims 66-71 have been added and are supported in the Specification on page 11, lines 16-27 and page 12, lines 1-15. No new matter has been added.

Applicants appreciate the Examiner's indication that Claims 16-19, 22, and 31 are allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. However, for the present, Applicant respectfully declines the opportunity to rewrite these claims in independent form but reserves the right to do so at a future time.

First 35 U.S.C. §102(b) Rejection

Claims 15, 23-29, 33-39, 61, and 63-65 stand rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Brenneman, et al. (U.S. Patent No. 5,645,566). This rejection is respectfully traversed.

According to the M.P.E.P. § 2131, "a claim is anticipated [under 35 U.S.C. § 102(b)] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *See also Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Independent Claim 15

Amended claim 15 provides for the following:

"loading an introducer with a sponge pledget by hydrating and compressing the pledget, the introducer having a lumen including a staging chamber and a delivery chamber"

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As shown in Figures 1 and 3, the “introducer 12 includes a staging chamber 34 for receiving an absorbable sponge pledget 40 and a delivery chamber 36 for receipt of a hydrated and compressed pledget from the staging chamber.” (Specification, page 7, lines 11-14). “The introducer allows the delivery of more absorbable sponge material through a smaller tract by hydrating and compressing the absorbable sponge material.” (Specification, page 5, lines 24-26). The pledget is hydrated within the staging chamber and then forced into the delivery chamber by injecting additional fluid with a syringe. (Specification, page 8, lines 1-7).

Brenneman teaches attaching the pledget to the distal end of a catheter and then inserting the catheter into the introducer. (Col. 9, lines 3-7). The introducer disclosed in Brenneman “has an open distal end positionable at the puncture, an external portion with an open proximal end, and an axial channel therebetween.” (Abstract). Brenneman, et al. teaches an embodiment of “a foam pad compression element **74** attached to the catheter distal end **34**. The foam pad element **74** is compressed when enclosed within the introducer **12**.” (Col. 7, lines 17-22). This is further stated in independent claims 1 and 19 that provide for the limitation of a “compression means attached to the distal end of the catheter.” (Col. 12, lines 44-45 and Col. 14, lines 51-52).

The Examiner stated that “if Brenneman discloses attaching the pledget to the end of the catheter and then discloses that the catheter (with pledget attached) is placed into the introducer, this satisfies the claimed limitation of loading the introducer with a sponge pledget. The step of inserting the catheter with the pledget attached to the catheter loads the introducer with the pledget.” (Office Action, page 4). Applicant respectfully disagrees. As

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amended, the introducer has a lumen including a staging chamber and a delivery chamber that receives the absorbable sponge. The absorbable sponge is not loaded into the introducer by means of attachment on a catheter. In fact, a catheter is not used in the claimed invention. Rather, the introducer has a lumen with a staging chamber and a delivery chamber whereby the pledget is hydrated within the staging chamber and then forced into the delivery chamber.

Thus, Brenneman, et al. can not be said to anticipate claim 15 since it does not teach "loading the introducer with a pledget of sponge, the introducer having a lumen including a staging chamber and a delivery chamber." Withdrawal of this rejection is respectfully requested.

Independent Claim 25

Independent claim 25 provides for the following limitation:

"loading the introducer over a guidewire positioned in the blood vessel by inserting the guidewire through the loaded pledget;

advancing the introducer with the loaded pledget through a tissue tract extending from a patient's skin to the puncture in the wall of the blood vessel without advancing the pledget relative to the introducer"

Thus, as claimed in amended claim 25, the introducer is loaded with the pledget and then advanced through the tissue tract without advancing the pledget relative to the introducer. On the other hand, Brenneman teaches attaching the pledget to the distal end of a catheter and then inserting the catheter into the introducer. (Col. 9, lines 3-7). The catheter (with pledget attached) is advanced into the introducer, which is already located in the tissue tract.

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Thus, Brenneman, et al. can not be said to anticipate claim 25 since it does not teach loading the introducer with a pledget and then advancing the introducer with the loaded pledget through the tissue tract without advancing the pledget relative to the introducer. Withdrawal of this rejection is respectfully requested.

Independent Claim 35

Amended claim 35 provides for the following limitation:

“loading an introducer with a pledget of sponge, the introducer having a lumen including a staging chamber and a delivery chamber.”

As shown in Figures 1 and 3, the “introducer 12 includes a staging chamber 34 for receiving an absorbable sponge pledget 40 and a delivery chamber 36 for receipt of a hydrated and compressed pledget from the staging chamber.” (Specification, page 7, lines 11-14). “The introducer allows the delivery of more absorbable sponge material through a smaller tract by hydrating and compressing the absorbable sponge material.” (Specification, page 5, lines 24-26). The pledget is hydrated within the staging chamber and then forced into the delivery chamber by injecting additional fluid with a syringe. (Specification, page 8, lines 1-7).

Brenneman teaches attaching the pledget to the distal end of a catheter and then inserting the catheter into the introducer. (Col. 9, lines 3-7). The introducer disclosed in Brenneman “has an open distal end positionable at the puncture, an external portion with an open proximal end, and an axial channel therebetween.” (Abstract). Brenneman, et al. teaches an embodiment of “a foam pad compression element 74 attached to the catheter distal end 34. The foam pad element 74 is compressed when enclosed within the introducer 12.” (Col. 7, lines 17-22). This is further stated in independent claims 1 and 19 that provide for

the limitation of a "compression means attached to the distal end of the catheter." (Col. 12, lines 44-45 and Col. 14, lines 51-52).

The Examiner stated that "if Brenneman discloses attaching the pledget to the end of the catheter and then discloses that the catheter (with pledget attached) is placed into the introducer, this satisfies the claimed limitation of loading the introducer with a sponge pledget. The step of inserting the catheter with the pledget attached to the catheter loads the introducer with the pledget." (Office Action, page 4). Applicant respectfully disagrees. As amended, the introducer has a lumen including a staging chamber and a delivery chamber that receives the absorbable sponge. The absorbable sponge is not loaded into the introducer by means of attachment on a catheter. In fact, a catheter is not used in the claimed invention. Rather, the introducer has a lumen with a staging chamber and a delivery chamber whereby the pledget is hydrated within the staging chamber and then forced into the delivery chamber.

Thus, Brenneman, et al. can not be said to anticipate claim 35 since it does not teach loading the introducer with a pledget of sponge, the introducer having a lumen including a staging chamber and a delivery chamber. Withdrawal of this rejection is respectfully requested.

Independent Claim 61

Independent claim 61 provides for the following limitations:

"loading an introducer with a pledget of a hemostatic material, wherein the loaded pledget is located in a distal end of the introducer;

advancing the introducer with the loaded pledget through a tissue tract extending from a patient's skin to the puncture in the wall of the blood vessel without advancing the pledget relative to the introducer"

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Thus, as claimed in claim 61, the introducer is loaded with the pledget and then advanced through the tissue tract without advancing the pledget relative to the introducer. On the other hand, Brenneman teaches attaching the pledget to the distal end of a catheter and then inserting the catheter into the introducer. (Col. 9, lines 3-7). The catheter (with pledget attached) is advanced into the introducer, which is already located in the tissue tract.

Thus, Brenneman, et al. can not be said to anticipate claim 61 since it does not teach loading the introducer with a pledget and then advancing the introducer with the loaded pledget through the tissue tract without advancing the pledget relative to the introducer. Withdrawal of this rejection is respectfully requested.

Second 35 U.S.C. §102(b) Rejection

Claims 25, 27-30, 32-34, and 61-65 also stand rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Janzen (U.S. Patent No. 5,391,183). This rejection is respectfully traversed.

Independent Claim 25

Amended claim 25 provides for the following:

“loading an introducer with a pledget of sponge;

loading the introducer over a guidewire positioned in the blood vessel by inserting the guidewire through the loaded pledget;

advancing the introducer with the loaded pledget through a tissue tract extending from a patient's skin to the puncture in the wall of the blood vessel without advancing the pledget relative to the introducer”

As claimed in amended claim 25, the introducer is loaded with the pledget and then advanced through the tissue tract without advancing the pledget relative to the introducer. As provided in the Specification, a user places the pledget into the introducer or alternatively, the introducer may be provided preloaded with a prepared pledget. (Specification, page 10, lines 15-20). In either case, the introducer is then advanced down through the skin and subcutaneous tissue. (Specification, page 11, lines 16-21). Thus, the pledget is loaded in the introducer before the introducer is loaded over a guidewire or into the skin of the patient.

The Examiner stated that with “respect to claim 25 and the Janzen reference, a pledget 57 is loaded into holder 29. The holder 29 is an introducer because it introduces the pledget into sheath 45. Claim 25 does not require that the introducer be loaded with the pledget before inserting the introducer into the patient. In fact claim 25 does not even recite that the introducer is inserted into the patient at all.” (Office Action, page 5). Claim 25 has been amended to further clarify the present invention. Amended claim 25 has been amended to state that the introducer is loaded with the pledget, then loaded with the guidewire, then advanced through a tissue tract without advancing the pledget relative to the introducer.

Janzen teaches the use of “a plunger . . . to push plug 93 into and through sheath 45 until the plug exits the sheath.” (Col. 9, lines 27-29). The plug is pushed through the sheath after the sheath is positioned in the tissue channel. (Col. 9, line 23). Thus, Janzen merely teaches how to push a plug through a sheath after the sheath is in the tissue channel and does not teach loading an introducer with a pledget before the introducer is into the skin of the patient.

Since Janzen does not teach or disclose all the limitations of the claimed invention, it can not anticipate the claimed invention. Withdrawal of this rejection is respectfully requested.

Independent Claim 61

Independent claim 61 provides for the following:

“loading an introducer with a pledget of a hemostatic material, wherein the loaded pledget is located in a distal end of the introducer;

advancing the introducer with the loaded pledget through a tissue tract extending from a patient’s skin to the puncture in the wall of the blood vessel without advancing the pledget relative to the introducer;

locating an exterior of the blood vessel; and

ejecting the pledget adjacent the exterior of the blood vessel.”

As claimed in claim 61, the introducer is loaded with the pledget and then advanced through the tissue tract without advancing the pledget relative to the introducer. As provided in the Specification, a user places the pledget into the introducer or alternatively, the introducer may be provided preloaded with a prepared pledget. (Specification, page 10, lines 15-20). In either case, the introducer is then advanced down through the skin and subcutaneous tissue. (Specification, page 11, lines 16-21). Thus, the pledget is loaded in the introducer before the introducer is loaded over a guidewire or into the skin of the patient.

Upon closer reading of Janzen, including the citations provided in the office action, Janzen teaches the plug being “slid down along the guide wire through tissue channel 9 until its front end reaches the wall of the femoral artery.” (Col. 7, lines 61-67 through Col. 8, lines 1-2). Janzen merely teaches how to push a plug through a sheath after the sheath is in the

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tissue channel and does not teach loading an introducer with a pledget before the introducer (or sheath) is into the skin of the patient.

Thus, since Janzen does not teach or disclose all the limitations of the claimed invention, it can not anticipate the claimed invention. Withdrawal of this rejection is respectfully requested.

Third 35 U.S.C. §102(b) Rejection

Claims 35, 37, 39-41 also stand rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Fowler (U.S. Patent No. 5,601,602). This rejection is respectfully traversed.

Amended claim 35 provides for the following:

“loading an introducer with a pledget of sponge, the introducer having a lumen including a staging chamber and a delivery chamber”

As shown in Figures 1 and 3, the “introducer 12 includes a staging chamber 34 for receiving an absorbable sponge pledget 40 and a delivery chamber 36 for receipt of a hydrated and compressed pledget from the staging chamber.” (Specification, page 7, lines 11-14). “The introducer allows the delivery of more absorbable sponge material through a smaller tract by hydrating and compressing the absorbable sponge material.” (Specification, page 5, lines 24-26). The pledget is hydrated within the staging chamber causing the pledget to swell, partially or fully blocking the lumen of the introducer. The hydrated pledget is then forced into the delivery chamber by injecting additional fluid with a syringe to force the pledget through the tapered section to the delivery chamber. (Specification, page 8, lines 1-7).

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Upon closer reading of Fowler, including the citations cited in the office action, Fowler teaches the use of “a preloaded insertion assembly 20 having a vessel plug 52. The insertion assembly of this embodiment consists of a syringe-like device with a plunger 54; a cylindrically shaped outer sleeve 56 and a cylindrically shaped inner sleeve 58.” (Col. 5, lines 64-67 through Col. 6, line 1). Thus, Fowler does not teach the use of an “introducer having a lumen including a staging chamber and a delivery chamber” as claimed in the present invention.

Since Fowler does not teach or disclose all the limitations of the claimed invention, it can not anticipate the claimed invention. Withdrawal of this rejection is respectfully requested.

Remaining Dependent Claims

All dependent claims depend from independent Claims 15, 25, 35, or 61 and thus include the limitations of their respective corresponding base claim. The base claim being allowable, the dependent claims must also be allowable.

In view of the foregoing, it is respectfully asserted that the claims are now in condition for allowance.

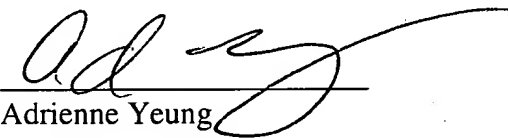
Request for Allowance

It is believed that this Response places the above-identified patent application into condition for allowance. Early favorable consideration of this application is earnestly solicited.

If, in the opinion of the Examiner, an interview would expedite the prosecution of this application, the Examiner is invited to call the undersigned attorney at the number indicated below.

Respectfully submitted,
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Dated: June 12, 2003


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